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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
of the Quality Control laboratory

Part 1	**General information**
Laboratory details	
Laboratory information	
Name of the laboratory	**M&L Laboratory Services (Pty) Ltd**
Corporate address of Laboratory	40 Modulus Road, Ormonde, Johannesburg, South Africa, 2091 GPS co-ordinates: S26°14'12.3" E028°00'25.0" Telephone No. +2711 661 7900 Fax No. +27 11 496 2239
Inspected Laboratory	
Licence	Medicines Control Council (MCC) of South Africa 0000000678 for analytical, microbiological and stability testing. Licence is valid until the 30 September 2019.
Summary of activities performed at the laboratory	

Types of Analysis	**Finished Products**	**Active Pharmaceutical ingredients**
Physical/chemical Analysis	pH, water content, loss on drying, water content (Karl fisher), friability, disintegration, tablet hardness, dissolutions, viscosity, density, uniformity of dosage units,	pH, water content, loss on drying, water content (Karl fisher), melting point, conductivity
Identification	IR, TLC, HPLC, UV, spectrophotometry and basic tests	IR, TLC, HPLC, UV spectrophotometry and basic tests
Assay, impurities and related substances	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and

		volumetric titrations Determination of related substances/impurities and degradation products	volumetric titrations Determination of related substances/impurities and degradation products

Inspection details	
Dates of inspection	12-13 December 2016
Type of inspection	Initial
Introduction	
History	M&L Laboratory Services (Pty) Ltd. is a contract testing laboratory based in Johannesburg, South Africa. The laboratory was opened in 1930 by two private individuals initially as a geochemical exploration laboratory. Over the years there have been many shareholders and the laboratory has expanded its scope of operations. It is currently a division of Bureau Veritas. There are five laboratories, namely, Pharmaceutical, Microbiological, Food, Water and Environmental/Occupational Hygiene. All laboratories are accredited to ISO 17025:2005 standards by the South African National Accreditation System (SANAS). In addition, the Pharmaceutical and Microbiological laboratories are licensed by the MCC. The following type of testing is performed: Pharmaceutical – stability testing for local manufacturers and multinationals, final product testing – post importation testing (ID and assay tests, description of products), raw material analysis (APIs and excipients). Microbiology – microbiological analysis of pharmaceutical samples, preservative efficacy testing. This was the first WHO inspection. Laboratory was inspected by MCC in February 2012. Laboratory was accredited to ISO 17025:2005.
Scope and limitations	
Areas inspected	See Part 2 below
Restrictions	N/A
Out of scope	Sterility testing, endotoxin testing

Abbreviations

AHU	air handling unit
ALCOA	attributable, legible, contemporaneous, original and accurate
API	active pharmaceutical ingredient
BDL	below detection limit

	CAPA	corrective actions and preventive actions		
	CC	change control		
	CFU	colony-forming unit		
	CoA	certificate of analysis		
	DQ	design qualification		
	EM	environmental monitoring		
	FAT	factory acceptance test		
	FMEA	failure modes and effects analysis		
	FPP	finished pharmaceutical product		
	FTA	fault tree analysis		
	FTIR	Fourier transform infrared spectrometer		
	GC	gas chromatograph		
	GMP	good manufacturing practice		
	HACCP	hazard analysis and critical control points		
	HPLC	high-performance liquid chromatograph		
	HVAC	heating, ventilation and air conditioning		
	IR	infrared spectrophotometer		
	IQ	installation qualification		
	KF	Karl Fisher		
	LAF	laminar air flow		
	LIMS	laboratory information management system		
	LoD	limit of detection		
	LOD	loss on drying		
	MB	Microbiology		
	MBL	microbiology laboratory		
	MR	management review		
	NMR	nuclear magnetic resonance spectroscopy		
	NRA	national regulatory agency		
	OQ	operational qualification		
	PHA	process hazard analysis		
	PM	preventive maintenance		
	PQ	performance qualification		
	QA	quality assurance		
	QC	quality control		
	QCL	quality control laboratory		
	QRM	quality risk management		
	RA	risk assessment		
	RCA	root cause analysis		
	SOP	standard operating procedure		

	TAMC	total aerobic microbial count		
	TFC	total fungi count		
	TLC	thin layer chromatography		
	URS	user requirements specifications		
	UV	ultraviolet-visible spectrophotometer		

Part 2	**Brief summary of the findings and recommendations (where applicable)**

Brief summary of the findings and comments

1. Organization and management

The laboratory was authorized to perform the tests under the MCC licence no. 0000000678, valid until the 30 September 2019.

Managerial and technical personnel were appointed in the laboratory to perform the relevant duties. Organizational charts, the organization and management structure and the position of the laboratory within the corporate organization were presented to the inspectors. Responsibilities were specified.

The laboratory maintained a registry of received consignments of samples and kept records of all incoming samples and accompanying documents.

2. Quality management system

The SOP "Quality Policy Statement" was presented to the inspectors. The Quality Policy included a description of the quality principles, the management system and outlined responsibilities in terms of management commitment.

The SOP "Management Review" was discussed. MR was performed according to the ISO 17025:2005 standard. The SOP referred to annual management meetings; and a standard agenda was included in the SOP. The agenda outlined discussions pertaining to, but not limited to: OOS, deviations, CAPAs, follow up of previous management review, customer complaints, the outcome of internal and external audits and customer feedback.

The last MR meeting was held on the 18th of November 2016 and a list of attendees and MR minutes were discussed.

The SOP "Quality Risk Management" and RA register were discussed.

Risk assessment "IR Integrity of Data" was discussed.

The SOP "Handling of Deviations" and the deviation register for 2016 were discussed. Deviations were classified as:

- Planned
- Unplanned
- Deviations from scheduled calibration of qualification schedules for equipment
- Deviations from SOPs.

Deviations were trended and discussed during the MR meeting.

The SOP "Complaints" and the customer complaint log book for 2016 were discussed.
The Laboratory Director / Quality Manager had overall responsibility for dealing with complaints. Complaints were categorized, but were not limited to the following:

- Turnaround time not met
- Query over results submitted
- OOS results submitted to customer without an investigation
- Lack of communication
- CoA errors

The SOP "Preventive Actions (PA)" and the PA register were discussed. The scope of this SOP covered the pro-active process of identifying opportunities for improvement, rather than reacting to the identification of existing problems or complaints.

The SOP "Corrective Action (CA)" and the CA register were discussed. The scope of this SOP covered non-conformities, either technical or concerning the management system, investigating the root causes, implementing appropriate CA and control thereof. The SOP explained CAs for non-conforming work.

The SOP "Change Control (CC)"and the CC register were discussed. This procedure was applicable to all corrective, preventive and continual improvement actions and to all changes that had an impact on any activity which might have an effect on the Company's procedures, outputs and services.
Changes were specified as:

- Permanent
- Temporary

The CC log books / registers were electronically maintained. Access to these log books / registers was password protected and was granted to QA personnel.
The SOP "Internal Audits" described that self-inspections were performed to ensure compliance with the requirements of the quality management system and ISO 17025:2005. The Quality Assurance (QA) department had overall responsibility for the management of self-inspections. SOP "Competency Criteria of Internal Auditors" was available and self-inspections were carried out by independent, competent auditors. The Audit Schedule was prepared by QA on an annual basis.

Internal audits were carried out using the relevant checklist and deficiencies made during the audit were classified as minor or major. CAPAs were logged on the "Corrective Action Request Register", recorded on the "Corrective Action Request Form" and submitted by the inspected department and evaluated by the QA department.

The laboratory participated in LGC proficiency testing schemes annually (HPLC test for API).

3. Control of documentation

Documented procedures were in place to control the documents. The authorized SOP "Master List", identifying the current version, status and distribution of documents, was available and was presented to the inspectors. Documents had a unique identifier, version number and date of implementation.

The SOP "Document and Data Control and Maintenance" described that all documents were assigned with a unique document number, title, revision number and effective date. Master documents were marked as such and controlled copies were marked as "authorised copy". SOPs were reviewed every four years and a revision history was maintained. A system of change control was in place to inform staff of new and revised procedures**.** The SOP "Writing Standard Operating Procedures (SOP) and Compiling Test Method Work Sheets" was available and described the requirements for writing SOPs, test method work sheets and validation protocols and reports.

4. Records

Original observations, calculations and derived data, calibration, validation and verification records and final results, were retained. The records included the data recorded in analytical notebooks.

5. Data processing equipment

The document "Master Qualification Plan" was discussed. Major systems and equipment were categorized into three groups. According to the Master Qualification Plan, a periodic review of the qualified status was performed.

The "Empower System Qualification Test Protocol for hardware (server)" was discussed. The qualification was performed by Waters.

The document "Connections AQT for Empower 3" Test Protocol for software" was discussed.

The Empower 3 Software 21 CFR Part 11 Compliance assessment report (performed by Waters) was discussed.

The SOP "Procedure for Use of the Empower Software" was discussed. The SOP defined software access levels and privileges.

The draft SOP "Procedure for Maintenance of the Empower Database" was presented to the inspectors. The SOP described the procedure for backup & archiving of Empower data.

6. Personnel

Generally the laboratory had sufficient personnel with the necessary education, training, technical knowledge and experience for their assigned functions. Staff members undergoing training were supervised and were assessed on completion of the training.

The Divisional Organogram was available.

The job description for the Operational Manager indicated that the Operational Manager was responsible for managing the daily operations and quality control of the laboratories. The Operational Manager was also responsible for ensuring approval and rejection of test operations and results, specifications and procedures, and process changes. The QA Manager and Operational Manager reported directly to the Director.

Job description, training records and evaluation of competency records were kept together in employee file.

The SOP "Personnel Training" specified the following types of training:

- Induction training
- Health and safety training
- Management system training
- SOP training
- Comprehensive training on laboratory test methods

Training effectiveness was evaluated through written assessment. Annual Training Programme was available and provided a matrix, indicating training requirements, and a training schedule, for all personnel for the year 2016, respectively.

SOP "Personnel Training" described that analysts would be trained on the relevant SOP for instruments as well as on test methods. A senior analyst/supervisor would witness testing to determine competency and proficiency, which would be recorded on the staff witnessing template.

SOP "Organization and Management" made provision for documenting job descriptions and for implementation of an approved signatory list, letters of appointment and confidentiality agreements. The "Conflict of Interest and Non-Disclosure Declaration" was available and was signed by each employee upon commencement of employment. The declaration was in place to ensure that laboratory management and personnel were not subject to commercial and financial pressures or conflict of interest that may adversely affect the quality of their work. Following signing of the declaration, employees were also required to immediately disclose any instance, where the employee found him/herself in a position of conflict.

7. Premises

The laboratory premises were equipped with a biometric access-control system.

Samples were stored in a temperature controlled room which was monitored with one data logger. An access controlled storage area was available, in the storage room, for the storage of scheduled substances and reference standards. Temperature mapping of the sample storage area was performed for 24 hours; no schematic diagram was available to indicate logger placement. The results of the temperature mapping study were not used to identify the location for permanent logger placement. A deep freeze and refrigerator were available in the laboratory for storage of cold chain samples. Daily checks for temperature in sample storage area not performed.

An archive room provided secure storage and allowed for easy retrieval of documents. The archive was designed to protect the documents from deterioration. Access to the archive was restricted to designated personnel. Documents were stored in movable metal cabinets. Back-up tapes and documents were stored off site at a contracted document archiving company.

Generally laboratory facilities were of a suitable size, construction and location. Rest and refreshment rooms were separate from laboratory areas.

8. Equipment, instrument and other devices

Document “Master Qualification Plan” was available. A periodic review of the qualified status was undertaken every five years. A list of major systems and equipment was available in the Master Qualification Plan. Systems and equipment which produced data were categorised as Group C and required validation. UV, IR, HPLC, GC, UPLC, dissolution bath, AA and autoclaves in Microbiological Laboratory were categorised as Group C.

Generally the laboratory had test equipment, instruments and other devices for the performance of the tests and/or calibrations, validations and verifications. It was noted that main instruments (e.g. HPLC, GC, UV etc.) calibration/verification and maintenance was contracted out to the third parties. Calibration status labels were attached to instruments.

Individual equipment operating SOPs were available and all laboratory instruments had usage log books.

HPLC and UPLC columns were stored in the original packages in the laboratory cupboards; however one column was observed to be stored in a loose piece of thin foam.

SOP “Injection Procedure and System Suitability Criteria for Routine HPLC and UPLC Analysis” was discussed. No SOP was available during the time of the inspection to describe the approach regarding manual integration. It was explained that manual integration was not permitted for application in assay testing.

Grade A volumetric glassware was used for analysis.

9. Contracts

Third party laboratories were contracted to perform a limited number of tests on behalf of M&L Laboratory Services (Pty) Ltd. Technical agreements (TA) with two contract laboratories were discussed. Contract laboratories were audited by the corporate QA unit. The TAs allowed the contract giver to audit the contract acceptor and the contract acceptor was not permitted to subcontract any work to a third party without written permission from the contract giver.

The list of approved service providers was presented to the inspectors.

10. Reagents

The SOP "Purchasing and Approval of Supplies" was discussed. Generally reagents and chemicals were purchased from approved suppliers and were accompanied by the certificate of analysis, and the material safety data sheet as appropriate. The approved suppliers list was presented to the inspectors. Suppliers were approved through the use of a paper-based check list. Reagents were logged into reagent register on receipt.

The SOP "Procedure for Storage of Chemicals in the Pharmaceutical Laboratory" was discussed. Upon opening the reagent for the first time, the date of opening and the signature of the person who opened the container were recorded on the label.

The SOP "Standardized and Non-standardized Solutions" was discussed. The SOP described the preparation, standardization and storage of volumetric solutions and the preparation and storage of non-standardised solutions, reference standard solutions and reagents. All volumetric solutions were checked on a monthly basis.

Reagents and volumetric solutions prepared in the laboratory were appropriately labelled.

HPLC grade water was used for analysis.

11. Reference substances and reference materials

The SOP "Procedure for Reference Standards Received in the Pharmaceutical Laboratory" was discussed. The SOP explained procedure for the receipt, usage, labelling, storage and recording of the Reference Standards (RS). The RS / Working Standards (WS) were delivered together with a sample. The laboratory was responsible for purchasing RS / WS, RS/WS were supplied by customers. Upon receipt, the RS / WS were labelled, with different colour labels, indicating storage conditions.

The analysts inspected RS / WS on a monthly basis to check for expiry and the laboratory supervisor was responsible for issuing the standards to the analyst. An internal label was placed on all RS / WS and a register of RS / WS was available.

12. Calibration, verification of performance and qualification of equipment, instruments and other devices

The Balance Room was equipped with four balances and a daily verification of each balance was performed. Balance accuracy and linearity was evaluated internally, on a monthly basis. Balance calibration was performed every six months, by an external contractor.

Mechanical and chemical calibration was performed for dissolution apparatus. Mechanical calibration was carried out on an annual basis by an external contractor.

The calibration certificates for the dissolution baths were available and prednisone tablets were used to perform the chemical calibration.

13. Traceability

The results of an analysis were traceable to reference substances, equipment and instruments used for analysis.

14. Incoming samples

The SOP "The Centralized Receipt and Storage of Samples" was discussed.

Upon receipt the samples were taken directly to the pharmaceutical laboratory (HPLC laboratory). The time and date of sample receipt was recorded on the parcel. Received samples were logged into the pre-printed sample receipt book and assigned a unique laboratory identification number. The identification number was traceable to analysis, equipment / instruments and CoA. Samples were stored appropriately in an access-controlled cupboard and/or refrigerator, where relevant.

Samples were checked visually by analysts.

15. Analytical worksheet

SOP "Procedure for the Use of Laboratory Workbooks/Log Sheets" was implemented to ensure that all data pertaining to the analytical samples/product was correctly recorded and retained. Workbooks were issued by the QA department. Workbooks were assigned a unique number which was reflected on each page of the workbook.

The laboratory workbooks were used by analysts each page of each laboratory workbook was reviewed and stamped as 'checked by" with the date and signature of the reviewer.

16. Validation of analytical procedures

SOP "Analytical Method Transfer" described that the client was responsible for providing the approved test method, reference standard/s and samples, required for testing of each product. The "Method Transfer Protocol" and "Report" were reviewed.

17. Testing

Test results were reviewed and evaluated. OOS results were investigated. The SOP HP040-43-7 "Injection Procedure and System Suitability Criteria for Routine HPLC and UPLC Analysis" was discussed. According to the SOP bracketing standard should be injected after every eight injections or two hours whichever is the shortest time.

18. Evaluation of test results

Test results were reviewed and evaluated.

The SOP "Investigation of Out of Specification Results / Laboratory Investigations", flow chart and register for 2016 were discussed. The SOP was written following USFDA guidelines. During the inspection it was advised that the company familiarize themselves with the MHRA "Out of Specification Investigation" guideline. OOS were trended and discussed during management review. OOS trends for 2016 were presented to the inspector.

SOP "Review, Approval of Analytical/Laboratory Documents" and SOP "Use of Significant Figures and Rounding" were discussed.

19. Certificate of analysis

The SOP "Certificate of Analysis for Finished Products" and SOP "Reporting of Results, Certificates and Reports" were discussed. The Laboratory Administrator was responsible for preparing the CoA. The CoA was checked and authorised by the Operations Manager, who was certified as the technical signatory by the SANAS.

20. Retained samples

The SOP "Procedure for the Disposal of Pharmaceutical Waste Generated in the Healthcare Department" was discussed. According to the SOP, finished product samples were retained for two weeks on site, in the retention cupboard, and stability samples, for one month, until the evaluation of the results was completed.

21. Safety

Emergency showers and eye wash equipment was provided.

PART 3 CONCLUSION

Based on the areas inspected, the people met and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report, as well as the corrective actions taken M&L Laboratory Services (Pty) Ltd, located at 40 Modulus Road, Ormonde, Johannesburg, South Africa, 2091was considered to be operating at an acceptable level of compliance with WHO Good Practices for Pharmaceutical Quality Control Laboratories for the following expertise:

Types of Analysis	Finished Products	Active Pharmaceutical ingredients
Physical/chemical Analysis	pH, water content, loss on drying, water content (Karl fisher), friability, disintegration, tablet hardness, dissolutions, viscosity, density, uniformity of dosage units,	pH, water content, loss on drying, water content (Karl fisher), melting point, conductivity
Identification	IR, TLC, HPLC, UV, spectrophotometry and basic tests	IR, TLC, HPLC, UV spectrophotometry and basic tests
Assay, impurities and related substances	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and volumetric titrations Determination of related substances/impurities and degradation products	HPLC (UV, fluorescence, RI, conductivity, PDA), UPLC (PDA), GC, UV, potentiometric and volumetric titrations Determination of related substances/impurities and degradation products

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the laboratory, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

PART 4

List of GMP guidelines referenced in the inspection

1. WHO Good Practices for Pharmaceutical Quality Control Laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957, Annex 1
   Short name: WHO TRS No. 961, 957), Annex 1
   http://www.who.int/medicines/publications/44threport/en/

2. WHO good manufacturing practices for pharmaceutical products: main principles. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-eight Report Geneva, World Health Organization, 2014 (WHO Technical Report Series, No. 986), Annex 2.
   Short name: WHO TRS No. 986, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_986/en/

3. WHO good practices for pharmaceutical microbiology laboratories. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 2
   Short name: WHO TRS No. 961, Annex 2
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

4. WHO Good Manufacturing Practices: water for pharmaceutical use. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fourth-six Report. Geneva, World Health Organization, 2012 (WHO Technical Report Series, No. 970), Annex 2
   Short name: WHO TRS No. 970, Annex 2
   http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_970/en/

5. WHO guidelines for sampling of pharmaceutical products and related materials. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-ninth Report. Geneva, World Health Organization, 2005 (WHO Technical Report Series, No. 929), Annex 4
   Short name: WHO TRS No. 929, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_929_eng.pdf?ua=1

6. WHO guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 5
   Short name: WHO TRS No. 961, Annex 5
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

7. Supplementary guidelines on good manufacturing practices: validation. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fortieth Report. Geneva, World Health Organization, 2006 (WHO Technical Report Series, No. 937), Annex 4
   Short name: WHO TRS No. 937, Annex 4
   http://whqlibdoc.who.int/trs/WHO_TRS_937_eng.pdf?ua=1

8. WHO Good Practices for Pharmaceutical Products Containing Hazardous Substances. WHO Expert on Specifications for Pharmaceutical Preparations. Forty-fourth Report. Geneva, World Health Organization, 2010 (WHO Technical Report Series, No. 957), Annex 2
   Short name: WHO TRS No. 957, Annex 2
   http://www.who.int/medicines/publications/44threport/en/

9. WHO good manufacturing practices for sterile pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 6
   Short name: WHO TRS No. 961, Annex 6
   http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

10. WHO guidelines on transfer of technology in pharmaceutical manufacturing WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 7
    Short name: WHO TRS No. 961, Annex 7
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

11. Model guidance for the storage and transport of time-and temperature-sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Fifth Report Geneva, World Health Organization, 2011 (WHO Technical Report Series, No. 961), Annex 9
    ***Short name: WHO TRS No. 961, Annex* 9**
    http://whqlibdoc.who.int/trs/WHO_TRS_961_eng.pdf?ua=1

12. General guidelines for the establishment maintenance and distribution of chemical reference substances. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-First Report Geneva, World Health Organization 2007 (WHO Technical Report Series, No.943) Annex 3
    Short name: WHO TRS No. 943, Annex 3
    http://whqlibdoc.who.int/trs/WHO_TRS_943_eng.pdf?ua=1

13. WHO guidelines on quality risk management. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Seventh Report Geneva, World Health Organization, 2013 (WHO Technical Report Series, No. 981), Annex 2
    Short name: WHO TRS No. 981, Annex 2
    http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/trs_981/en/

14. WHO Technical supplements to Model Guidance for storage and transport of time – and temperature – sensitive pharmaceutical products. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Forty-Ninth Report Geneva, World Health Organization, 2015 (WHO Technical Report Series, No. 992), Annex 5
Short name: WHO TRS No. 992, Annex 5
http://www.who.int/medicines/areas/quality_safety/quality_assurance/expert_committee/WHO_TRS_992_web.pdf

15. Guidance on good data and record management practices. WHO Expert Committee on Specifications for Pharmaceutical Preparations. Fifties Report Geneva, World Health Organization, 2016 (WHO Technical Report Series, No. 996), Annex 5
Short name: WHO TRS No. 996, Annex 5
http://www.who.int/medicines/publications/pharmprep/WHO_TRS_996_annex05.pdf